

Ŭ

. .

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STEPHEN WENDELL & LISA WENDELL, as successors in interest to MAXX WENDELL, deceased,

Plaintiffs,

v.

JOHNSON & JOHNSON; CENTOCOR, INC.; ABBOTT LABORATORIES; SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICALS USA; GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA; PAR PHARMACEUTICAL, INC.,

Defendants.

No. C 09-04124 CW

ORDER DENYING
WITHOUT PREJUDICE
DEFENDANT GSK'S
MOTION FOR SUMMARY
JUDGMENT.
(Docket No. 150)

Defendant GlaxoSmithKline LLC (GSK), formerly known as and served and sued in this action as SmithKline Beecham d/b/a GlaxoSmithKline, moves for summary judgment under Federal Rule of Civil Procedure 56. Docket No. 150. Plaintiffs oppose the motion under Federal Rule of Civil Procedure Rule 56(d). Having considered all of the parties' submissions, the Court denies without prejudice GSK's motion for summary judgment.

 $^{^{1}}$ Former Federal Rule of Civil Procedure 56(f) was amended in 2010. It is now set forth in Federal Rule of Civil Procedure 56(d). "Subdivision (d) carries forward without substantial changes the provisions of former subdivision (f)." Fed. R. Civ. P. 56 advisory committee note.

BACKGROUND

Plaintiffs bring this pharmaceutical products liability action, alleging that Defendants failed adequately to warn about certain risks posed by Defendants' drug products, specifically three prescription drugs: Remicade, Humira and 6-mercaptopurine (also known as Purinethol and 6-MP). Plaintiffs contend that these drugs, used either alone or in combination, resulted in their son Maxx Wendell's development of hepatosplenic T-Cell lymphoma (HSTCL) in 2007, and his eventual death a few months later from the illness.

Plaintiffs filed their suit originally in San Francisco
County Superior Court on July 2, 2009. Defendant Abbott
subsequently removed the action to federal court on September 4,
2009. Shortly thereafter Abbott moved to dismiss Plaintiffs'
claims, which the Court did, without prejudice and with leave to
amend on January 20, 2010. On February 9, 2010 Plaintiffs filed
their first amended complaint, which Defendants then moved to
dismiss on the pleadings. On June 14, 2010, the Court denied
Abbott's motion to dismiss, but granted the other Defendants'
motion to dismiss with leave to amend. Plaintiffs filed their
second amended complaint on June 10, 2010, and a third amended
complaint on February 2, 2011.

The Court's June 3, 2010, Case Management Order set February 2, 2011 as the deadline for fact discovery, and September 14, 2011 for the completion of expert discovery.

LEGAL STANDARD

Summary judgment is properly granted when no genuine and disputed issues of material fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Eisenberg v. Ins. Co. of N. Am., 815 F.2d 1285, 1288-89 (9th Cir. 1987).

The moving party bears the burden of showing that there is no material factual dispute. Therefore, the court must regard as true the opposing party's evidence, if supported by affidavits or other evidentiary material. Celotex, 477 U.S. at 324; Eisenberg, 815 F.2d at 1289. The court must draw all reasonable inferences in favor of the party against whom summary judgment is sought.

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Intel Corp. v. Hartford Accident & Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991).

Material facts which would preclude entry of summary judgment are those which, under applicable substantive law, may affect the outcome of the case. The substantive law will identify which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

Federal Rule of Civil Procedure 56(d) provides that the court may deny or continue a motion for summary judgment "[i]f a party opposing the motion shows by affidavit that, for specified

reasons, it cannot present facts essential to justify its opposition." The requesting party must show that (1) it has set forth in affidavit form the specific facts it hopes to elicit from further discovery, (2) the facts sought exist and (3) the sought-after facts are essential to oppose summary judgment. Family Home & Fin. Ctr., Inc. v. Fed. Home Loan Mortgage Corp., 525 F.3d 822, 827 (9th Cir. 2008). Where a summary judgment motion is filed early in the litigation before a party has had a realistic opportunity to pursue discovery relating to its theory of the case, district courts should grant a Rule 56(d) motion "fairly freely." Burlington Northern Santa Fe R. Co. v. Assinboine and Sioux Tribes of Fort Peck Reservation, 323 F.3d 767, 773 (9th Cir. 2003).

DISCUSSION

Defendant GSK argues that it is entitled to summary judgment because Plaintiffs lack evidence that the particular risk of HSTCL in connection with Purinethol was known or knowable when GSK ceased distributing the drug. GSK sold Purinethol in the United States from the time the FDA approved its New Drug Application (NDA) in 1953 until GSK sold the Purinethol NDA to Teva Pharmaceutical Industries Ltd. on July 1, 2003. GSK asserts that there were no reports of HSTCL in any human subjects in any of the clinical trials conducted in connection with its NDA for Purinethol. Nor did GSK receive any adverse event reports of HSTCL associated with Purinethol, either singly or in combination

25

26

27

28

1

with other drugs, before July 1, 2003. In searching its adverse event report files, from the date of the NDA approval in 1953 through the present, GSK found that the first report of HSTCL associated with use of Purinethol was published in the medical literature in 2005, and GSK did not receive a direct report of HSTCL associated with use of Purinethol at any time prior to 2008.

Plaintiffs respond that they are entitled to a continuance under Rule 56(d) because they have propounded discovery requests on all Defendants in this action, but have not received complete responses thus far. Through these requests Plaintiffs have sought discovery regarding "every and all adverse experiences and/or events" concerning the use of Purinethol. Declaration of Kevin Haverty, Ex. 4, Request for Production No. 9. Additionally, Plaintiffs have requested any and all documents, materials and other data bearing any connection to "the potential association and/or risk of lymphoma and in particular hepatosplenic T-cell lymphoma (HSTCL) associated with the ingestion of 6-MP, and/or its chemical bioequivalent, reported to and/or known by Defendant or of which Defendant was or is otherwise aware." Id., Ex. 4, Request for Production No. 13. Plaintiffs contend that, given the broad nature of the discovery sought, Defendants' incomplete responses have hampered their ability to secure the evidence necessary to respond to Defendant GSK's motion.

Plaintiffs served their discovery requests, including interrogatories and requests for the production of documents, on

July 13, 2010. Defendants submitted preliminary responses between August 25, 2010 and November 15, 2010, with Defendant GSK responding last. Defendants, including GSK, responded that documents necessary to comply with Plaintiffs' requests would be provided subject to entry of a protective order. However, a dispute arose as to the terms of the protective order and the parties did not submit a Stipulated Protective Order to the Court until April 18, 2011. Docket No. 161.

Thus, Defendants have given incomplete discovery responses. In particular, GSK's responses have been narrow in scope, touching only on reports of associations between Purinethol and HSTCL, while omitting information about the existence or non-existence of any connection between Purinethol and other types of lymphomas.

Other lymphomas or adverse events may be relevant to determining whether GSK knew or could have known about the risk posed by Purinethol with respect to HSTCL. Because Plaintiffs have identified specific facts that they seek through additional discovery and they have not had an adequate opportunity to pursue discovery related to the theory of their case, GSK's motion for summary judgment is premature and, therefore, denied without prejudice.

//

 $_{26}$ /

27 | /

28 | //

Case 4:09-cv-04124-CW Document 163 Filed 04/19/11 Page 7 of 7

United States District Court For the Northern District of California

CONCLUSION

Defendant GSK's motion for summary judgment is denied without prejudice to re-noticing on July 28, 2011 or thereafter. Docket No. 150.

IT IS SO ORDERED.

Dated: 4/19/2011

CLAUDIA WILKEN

United States District Judge